

**UNITED STATES DISTRICT COURT FOR
THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

THE STATE OF TEXAS,
ex rel.
ALLISON ZAYAS and
TRACY MIKSELL-BRANCH,

Plaintiffs,

V.

ASTRAZENECA, L.P., and
ASTRAZENECA PHARMACEUTICALS,
L.P.,

Defendants.

[illegible]

Case No. 1:14-cv-01111-RP

[Cause No. D-1-GN-13-003530
in the 353rd Judicial District,
Travis County, Texas]

PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO MOTION TO REMAND

I. INTRODUCTION

Defendants attempt to support the removal of this state law enforcement action by mischaracterizing Plaintiffs’ supporting references to federal law and by raising a federal-law-based defense to a theory of recovery Plaintiffs did not plead. *See* Opp. 1, 8, 10, 11. It is settled law that references to FDCA violations—such as those listed by Defendants in their opposition—are insufficient to confer federal jurisdiction. *See Merrell Dow Pharms. v. Thompson*, 478 U.S. 804, 805–06 (1986) (holding allegations “that the drug . . . was ‘misbranded’ [under] the Federal . . . FDCA” and that “the ‘violation of said federal statutes directly . . . caused the injuries” did not confer jurisdiction). Similarly, Defendants’ Medicaid Act argument both fails to meet the *Grable/Singh* test and amounts to a defense to allegations that were not pled.

Despite Defendants’ misdirection, the facts remain that this state law enforcement action alleges only state law claims related to Defendants’ fraudulent conduct toward the Texas Medicaid program and seeks only the appropriate remedies under Texas statutory and common law.

II. ARGUMENT AND AUTHORITIES

“[A]ny doubt as to the propriety of removal should be resolved in favor of remand,” and Defendants fail to meet the burden of proving they prevail on all four *Grable/Singh* prongs. *See In re Hot-Hed, Inc.*, 477 F.3d 320, 323 (5th Cir. 2007); *see also Singh v. Duane Morris LLP*, 538 F.3d 334, 338 (5th Cir. 2008).

A. Federal Law is Unnecessary

Defendants incorrectly assert that “plaintiffs’ . . . claims . . . *depend on* whether plaintiffs can demonstrate AstraZeneca misbranded Seroquel in violation of the FDCA.” Opp. 5 (emphasis

added). None of Plaintiffs' state-law claims includes "misbranding" as an element.¹ The elements relating to Defendants' conduct that Plaintiffs must prove to prevail under the TMFPA are misrepresentation, falsity, or omission. Under the Texas common law, Plaintiffs must prove misrepresentation, failure to disclose material facts, false information, unlawful acts, or failure to keep a promise on which a victim reasonably relied. State law is independently sufficient to sustain every cause of action in the Petition as written. In making their argument that proof of FDCA violations is essential for Plaintiffs to prevail, Defendants ignore the plain words of the Petition, including each of the paragraphs referencing violation of state misbranding law. *See, e.g.*, Pet. ¶¶ 75, 82, 92, 104, 108, 116.² Moreover, because misbranding is not an element that must be proven to support Plaintiffs' claims, the allegations of Defendants' pervasive false and misleading behavior directed at the Texas Medicaid program would, alone, fully support each cause of action.³ Therefore, it is not necessary for Plaintiffs to prove a violation of the federal FDCA, or any other federal law, in order to prevail.

B. No Federal Issues are Substantial

Defendants rely on Judge Weinstein's unique analysis of FDCA allegations in the removal context to support the notion that "off-label marketing claims . . . necessarily raise substantial federal questions." Opp. 8–9 (citing *Montana ex rel. McGrath v. Eli Lilly and Co.*, Nos. 04-MD-1596, 07-CV-1933, 2008 WL 398378 (E.D.N.Y. Feb. 12, 2008)). However, Judge Weinstein himself acknowledges that many courts have disagreed with this analysis at length. *Id.* at *4. Indeed,

¹ Because Plaintiffs raised this same argument in the Motion to Remand, Mot. 4, Defendants' statement that "Plaintiffs do not dispute that almost all of their claims, as pled, hinge on whether AstraZeneca 'misbranded' its products" is incorrect. Opp. 7.

² Each of the paragraphs relating to misbranding cited by Defendants, Opp. 2 (citing Pet. ¶¶ 75, 82, 92, 104, 108, 116) explicitly alleges violations of state law. Whether a citation to the state misbranding law, or other state laws, is provided is immaterial in a notice pleading regime.

³ *See, e.g.*, Pet. ¶¶ 2, 66, 68, 76–78, 80, 84, 87–91, 101–03, 105, 107, 111–15, 117, 119, 121, 129–31, 144–47.

Plaintiffs cite no fewer than 16 state Medicaid fraud enforcement actions remanded by 11 different federal courts because analogous federal issues were not sufficient to confer federal jurisdiction. *See* Mot. and authorities cited therein (including 10 cases where, as here, defendants raised both the FDCA and the Medicaid Act as bases of jurisdiction). Further, Judge Weinstein does not address the fact, applicable in both FDCA and Medicaid Act contexts, and addressed more fully below, that Congress intended some state enforcement of both laws. *McGrath*, 2008 WL 398378, at *6.

**C. Federal Jurisdiction Over this State Law Enforcement
Action Would Upend the Required Federal/State Judicial Balance**

Defendants fail to make the required showing that jurisdiction over this state law enforcement action would not disrupt the congressionally-approved federal/state judicial balance. This fourth *Grable/Singh* prong requires an examination of congressional intent to ensure that the federal/state judicial balance is not upended by allowing every state case referencing federal standards into federal court. *See Grable*, 545 U.S. at 318 (discussing *Merrell Dow* and noting that § 1331 requires “sensitive judgments about congressional intent”). In conducting this required analysis, it remains important that Congress did not create a private right of action under the FDCA specifically. *See Grable*, 545 U.S. at 316 (leaving intact *Merrell Dow*’s determination that FDCA allegations did not confer federal jurisdiction and stating that “[t]he Court saw the missing cause of action . . . as a missing welcome mat, required in the circumstances . . .”). Similarly, courts have seized on the fact that the Medicaid Act requires states to seek recovery from liable third parties to find no federal jurisdiction over state fraud cases implicating both the FDCA and the Medicaid Act because jurisdiction “would not be consistent with congressional judgment about the sound division of labor between states and the federal courts.” *Mississippi ex rel. Hood v. Ortho-McNeil-Janssen Pharms., Inc.*, No. 1:08CV166-SA-JAD, 2009 WL 561575, at *3 (N.D. Miss. Mar. 4, 2009); *South Carolina ex rel. McMaster v. Janssen Pharmaceutica, Inc.*, No. 6:07-1452-HMH, 2007 WL

2022173, at *3 (D.S.C. Jul. 10, 2007); *see also Louisiana v. Pfizer, Inc.*, No. 3:13-cv-00727-BAJ-RLB, 2014 WL 3541057, at *7, *9 (remanding case implicating FDCA and Medicaid Act, and stating “[A]llowing these state law claims [into federal court] would result in the removal of nearly any action by a state’s attorney general against a pharmaceutical company regarding prescription drugs.”).

Defendants ignore congressional intent and attempt to make this prong hinge on the relative judicial efficiency and competence of state and federal courts for a particular case. Opp. 12. Yet even if that were the sole criterion to be considered for this prong, the inconvenient fact is that no TMFPA case filed by the State has remained in federal court following a motion to remand.⁴ Thus, Travis County courts have ruled on many disputed issues in TMFPA cases over the last fifteen years and are fully competent to adjudicate any issues raised. Moreover, Defendants’ bald assertion that “[t]he TMFPA is ‘analogous’ to the FCA and application of FCA interpretation is appropriate,” Opp. 13, conveniently ignores that there are very substantial, material differences between the FCA and the TMFPA, both in determining liability and in assessing appropriate civil remedies.⁵

**D. Defendants’ Medicaid Act Argument Also Fails
Because it is a Defense that is Insufficient to Confer Federal Jurisdiction**

Defendants’ Opposition makes clearer that their Medicaid Act argument is really a preemption defense. Defendants first anticipate a theory of recovery, unstated in the Petition, and

⁴ *See* Pl.’s Opp. Mot. Trans. 10 n.15 (listing numerous TMFPA cases competently handled in Texas state court).

⁵ For example, the TMFPA does not require the proving up of “false claims”; instead, the TMFPA sets out unlawful acts that give rise to liability for fraudulent conduct. *Compare* 31 U.S.C. §§ 3729(1)(A)-(G) *with* Tex. Hum. Res. Code §§ 36.002(1)-(13). With respect to recovery, *Compare* 31 U.S.C. § 3729(1) *with* Tex. Hum. Res. Code §§ 36.052(a)(1). Defendants’ reliance on *U.S. ex rel. Williams v. McKesson Corp.*, No. 3:12-cv-0371, 2014 WL 3353247, at *4 (N.D. Tex. July 9, 2014), is unavailing, because the parties there, not including the State of Texas, simply agreed to assume the TMFPA claims were analogous to the FCA claims. In this case, the TMFPA provisions alleged have no FCA analogue.

argue that this theory would conflict with federal law. *See* Opp. 1, 8, 10, 11. But, Plaintiffs would not need to prove that their theories are consistent with federal law in the absence of Defendants raising this defense. The well-pleaded complaint rule strictly bars such a basis for jurisdiction. *Franchise Tax Bd.*, 463 U.S. at 14 (It is “settled law” that “a case may not be removed to federal court on the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff’s complaint, and even if . . . the defense is the only question truly at issue in the case.”). As the Western District recognized in another TMFPA action against a drug manufacturer, Defendants “arguing that [they] will prevail by proving . . . compliance with [a] federal standard” are raising “no more than a federal defense.” *See Texas v. Ranbaxy Pharms., Inc.*, No. 1:12-cv-925-SS, at 7–8 (W.D. Tex. Nov. 8, 2012) [attached to Mot., Ex. A] (order granting remand motion); *see also Merrell Dow*, 478 U.S. at 808, 815–16 (stating the well-pleaded complaint rule and noting the distinction between a preemption defense and a federal question); *Missouri ex rel. Nixon v. Mylan Labs., Inc.*, No. 4:06CV603 FLEA, 2006 WL 1459772 (E.D. Mo. May 23, 2006) (remanding where supposed federal Medicaid Act issues are not “readily apparent, rather, in order to ascertain the basis . . . the Court is required to look beyond plaintiffs’ petition to regulations which set forth specific drugs which are entitled to Medicaid coverage”). Even if Plaintiffs had raised this issue, any such federal Medicaid Act issues are not sufficiently “necessary,” “disputed,” “substantial,” and “balance disturbing” to confer federal jurisdiction. Mot. 9–14.⁶

III. CONCLUSION

For these reasons, in addition to the reasons stated in Plaintiffs’ opening brief, Plaintiffs respectfully request that this case be remanded.

⁶ Defendants’ citation to *Alaska v. Janssen Ortho, LLC*, No. 3:1-cv-00002, Opp. 10–11, is unavailing because in the complaint in that case, unlike the petition here, plaintiffs specifically sought to recoup reimbursements for prescriptions written for indications that were “not medically accepted.” Hr’g, April 29, 2011, ECF No. 57, at 5:10–7:19.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 10, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all counsel of record by electronic mail or by facsimile.

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